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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,683	07/19/2002	James S. Nowick	UCIVN-001US	3685

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,683	Applicant(s) NOWICK ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 10, 11, drawn to a compound corresponding to the structural formula provided in claim 1.
2. Claims 2-5, drawn to a peptide or peptidomimetic which incorporates a compound according to Group 1.
3. Claims 6-9, drawn to a composition comprising a compound according to claim 1 in combination with a second agent.
4. Claims 12-15, drawn to a method of causing dimerization of a compound.
5. Claims 16, 20, 21, drawn to a method of treating a disease.
6. Claims 23-26, drawn to a method for identifying compounds which participate in *beta*-sheet interaction with a protein.
7. Claims 27-29, drawn to a method of peptide synthesis.
8. Claims 30-31, drawn to a peptide or amino acid.

None of claims 17-19 or 22 is grouped. Each of these claims recites "the disease or disorder", a phrase which lacks antecedent basis in both claim 12 and claim 13. It is assumed that applicants intend for 17-19 and 22 to be dependent on claim 16, rather than claim 13. In the event that claims 17-19 and 22 are amended such that antecedent

basis for the phrase at issue is provided, these claims will be grouped appropriately.

The claimed inventions are distinct.

Groups 1 and 2 are regarded as distinct, since Group 1 is drawn to compounds of the indicated structure, whereas Group 2 is drawn to a peptide or peptidomimetic that contains the structure depicted in claim 1. Nevertheless, in the event that Group 1 is elected, and claims therein found allowable, it is more likely than not that Group 2 will be rejoined therewith, but subject to the same limitations on structure which may have been introduced into the Group 1 claims.

Groups 1 and {4, 5} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). Nevertheless, in the event that Group 1 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination provided that the limitations present in the claims (drawn to compounds) are incorporated into the method claims [*In re Ochiai* (37 USPQ2d 1127)]. On the other hand, Groups 1 and 6 are not related as product and process of use. Claim 1 is drawn to a compound that has the indicated formula, whereas claim 23 requires the use of a compound which “comprises” the structural formula that is recited in claim 1.

Accordingly, there is no obligation to rejoin Group 6 with Group 1 (in the event that Group 1 is elected). However, in the event that Group 1 is elected, the possibility of rejoining Group 6 is not necessarily precluded.

Similar to the foregoing, Groups 8 and 7 are related as product and process of use. In the event that Group 8 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

- In the event that any of Groups 1, 4 or 6 is chosen for initial examination, election of a specific compound is required, in which all substituent variables are fully accounted for.
- In the event that group 2 is chosen for initial examination, election of a specific compound is required, in which all substituent variables are fully accounted for. Also required is a statement as to whether it is a peptide or a protein or a peptidomimetic that has incorporated the compound according to claim 1.
- In the event that group 3 is chosen for initial examination, election of a specific compound is required, in which all substituent variables are fully accounted for. Also required is selection of a specific agent that meets the requirements of one of

claims 6-9, accompanied by a statement as to which of the following criteria the agent meets: (a) causes the agent to mimic *beta*- strands, or (b) causes the agent to block *beta*-sheet dimerization of proteins, or (c) causes the agent to block protein-protein *beta*-sheet interactions or (d) causes the agent to interact with a protein by *beta*-sheet formation.

- In the event that group 5 is chosen for initial examination, election of a specific compound is required, in which all substituent variables are fully accounted for. Also required is election of a specific disease or disorder which is to be treated.
- In the event that Group 7 or 8 is chosen for initial examination, election of a specific Fmoc* - bearing amino acid or peptide is required.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be

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rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1653